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13th Pharmaceutical Industry Conference

Houston, Texas

September 11 - 12, 2007

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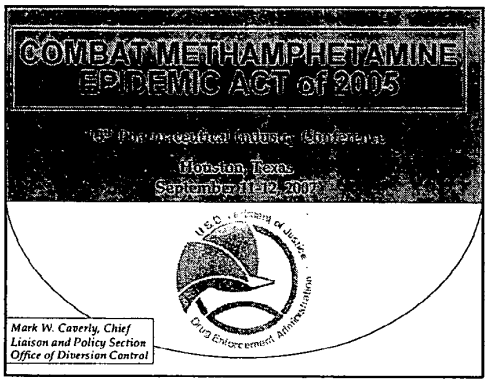
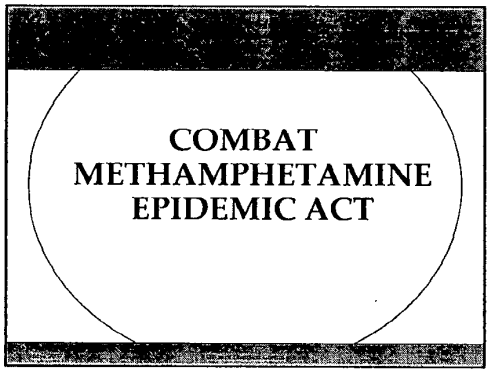
Total Number of Attendees = 137
Total Number of Companies = 72


COMBAT METHAMPHETAMINE EPIDEMIC ACT of 2005
Houston, Texas
September 11-12, 2007
Mark W. Caverly, Chief
Liaison and Policy Section
Office of Diversion Control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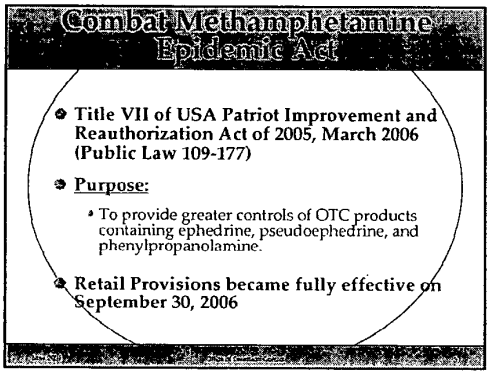
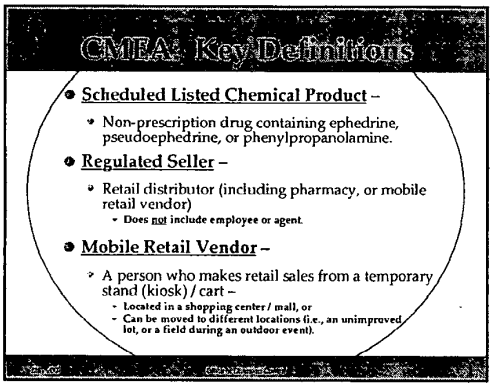
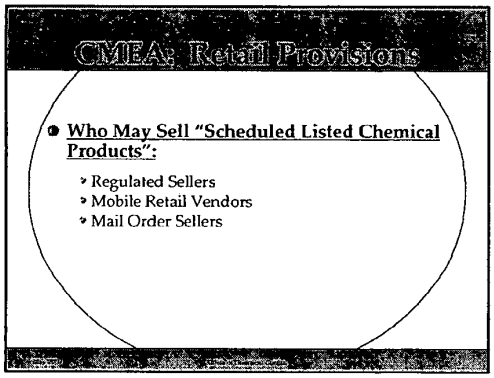
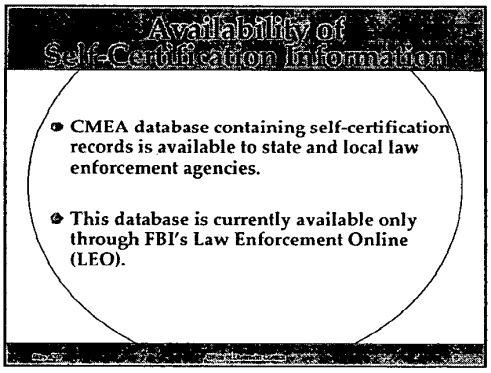
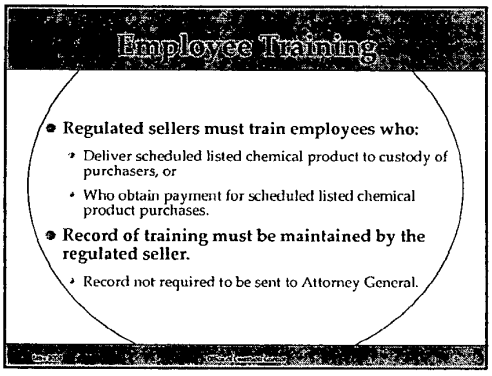
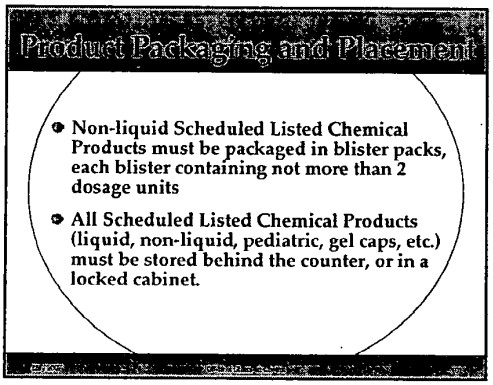

Combat Methamphetamine Epidemic Act
Title VII of USA Patriot Improvement and Reauthorization Act of 2005, March 2006 (Public Law 109-177)
Purpose:
To provide greater controls of OTC products containing ephedrine, pseudoephedrine, and phenylpropanolamine.
Retail Provisions became fully effective on September 30, 2006

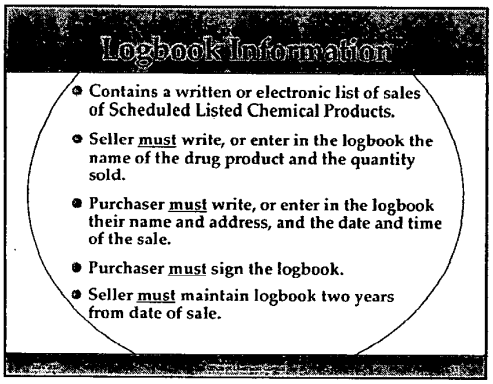


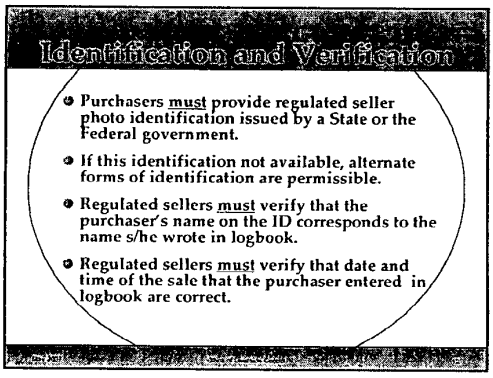


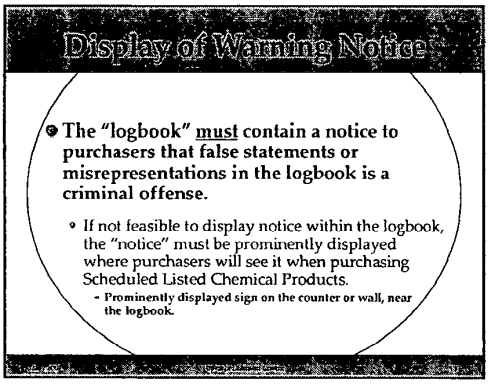


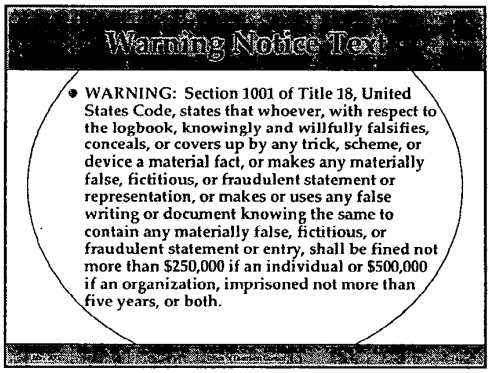


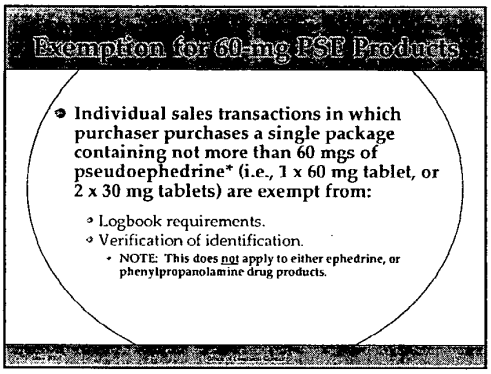












Disclosure of Logbook Information

- Logbook information shall be provided as appropriate to Attorney General and to State and local law enforcement.
- Law prohibits accessing, using or sharing information for any purpose other than to ensure compliance with Title 21, U.S. Code, or to facilitate product recall to protect public health and safety.

Daily Sales Limit

- Regulated sellers cannot sell more than 3.6 grams per day to each purchaser of Scheduled Listed Chemical Products, regardless of number of transactions.
- Daily sales limit per chemical.
- Refer to the charts on the next two slides for the amount of tablets or liquids that equals 3.6 grams.

CMEA: Point-of-Sale Requirements

- Effective April 8, 2006:
  - Daily sales limit 3.6 grams per day per customer.
  - Non-liquids packaged in blister pack only – 2 dosage units / blister pack.

Ingredient	# of Tablets (base)
25 mg Ephedrine HCl	175
25 mg Ephedrine Sulfate	186
30 mg Pseudoephedrine HCl	146
60 mg Pseudoephedrine HCl	73
120 mg Pseudoephedrine HCl	36
30 mg Pseudoephedrine Sulfate	155
60 mg Pseudoephedrine Sulfate	77
120 mg Pseudoephedrine Sulfate	38
Phenylpropanolamine	FDA issued a voluntary recall on this ingredient. Veterinary use is by Rx only.

CMEA: Point-of-Sale Requirements

- **Effective April 8, 2006:**
  - Daily sales limit 3.6 grams per day per customer.
  - Liquid quantities.

Ingredient	# of Milliliters (base)
6.25 mg / 5 ml Ephedrine HCl	3,515
15 mg / 1.6 ml Pseudoephedrine HCl	468
7.5 mg / 5 ml Pseudoephedrine HCl	2,929
15 mg / 5 ml Pseudoephedrine HCl	1,464
15 mg / 2.5 ml Pseudoephedrine HCl	732
30 mg / 5 ml Pseudoephedrine HCl	732
30 mg / 2.5 ml Pseudoephedrine HCl	366
60 mg / 5 ml Pseudoephedrine HCl	366
Phenylpropanolamine	FDA issued a voluntary recall on this ingredient. Veterinary use is by Rx only.

Mail Order Distributors

- **Requirements:**
  - Verify identification prior to shipping product,
  - Monthly mail order reports,
  - Daily sales limit of 3.6 grams, and
  - 30-day sales limit of 7.5 grams.
- **Not Required:**
  - Self-certification,
  - Employee training, and
  - Maintain a logbook.

Verification of Identities

- **Mail order distributors must verify identity of purchasers and recipients *(if different than purchaser)*, prior to shipping product.**
- **Identity verified by purchaser providing copy of ID to mail order distributor prior to shipment of product.**
  - Law / regulations do not stipulate how ID must be provided. Some examples, include:
    - Mailing,
    - Faxing, and
    - Scanning and e-mailing.

Monthly Mail Order Report

- **Mail order distributors must file monthly mail order reports regarding their sales of Scheduled Listed Chemical Products.**
  - Reporting requirement same as before, except must now specify method used to verify identity of purchaser and, where applicable, recipient.

Mail Order Sales Limits

- **Daily Limit:**
  - 3.6 gram per purchaser regardless of the number of transactions.
- **30-Day Limit:**
  - 7.5 grams per purchaser regardless of the number of transactions.
  - 30-day sales limit per chemical product.
- **Refer to the charts on the next two slides for the amount of tablets or liquids that equals 3.6 and 7.5 grams.**

CMEA: Mail-Order Sales (tablets)

- Daily sales limit 3.6 grams per day per customer.
- 30-day sales limit 7.5 grams per customer.
- Confirm identity of purchaser prior to shipping.

Ingredient	Tablets (3.6 gm)(base)	Tablets (7.5 gm)(base)
25 mg Ephedrine HCl	175	366
25 mg Ephedrine Sulfate	186	389
30 mg Pseudoephedrine HCl	146	305
60 mg Pseudoephedrine HCl	73	152
120 mg Pseudoephedrine HCl	36	76
30 mg Pseudoephedrine Sulfate	155	324
60 mg Pseudoephedrine Sulfate	77	162
120 mg Pseudoephedrine Sulfate	38	81
Phenylpropanolamine	FDA issued a voluntary recall on this ingredient. Veterinary use is by Rx only.	

CMEA: Mail-Order Sales (Liquid)

- Daily sales limit 3.6 grams per day per customer.
- 30-day sales limit 7.5 grams per customer.
- Confirm identity of purchaser prior to shipping.

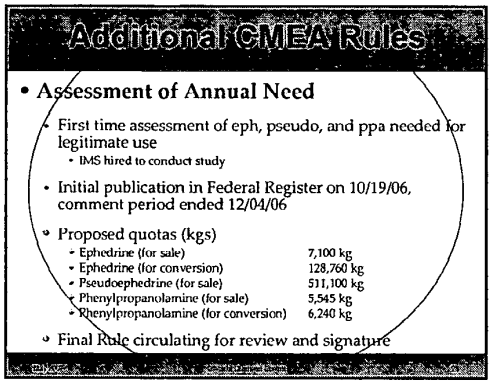
Ingredient	# of Milliliters (3.6 gm/base)	# of Milliliters (7.5 gm/base)
6.25 mg / 5 ml Ephedrine HCl	3,515	7,323
15 mg / 1.6 ml Pseudoephedrine HCl	468	976
7.5 mg / 5 ml Pseudoephedrine HCl	2,929	6,103
15 mg / 5 ml Pseudoephedrine HCl	1,464	3,051
15 mg / 2.5 ml Pseudoephedrine HCl	732	1,525
30 mg / 5 ml Pseudoephedrine HCl	732	1,525
30 mg / 2.5 ml Pseudoephedrine HCl	366	762
60 mg / 5 ml Pseudoephedrine HCl	366	762
Phenylpropanolamine	FDA issued a voluntary recall on this ingredient. Veterinary use is by Rx only.	

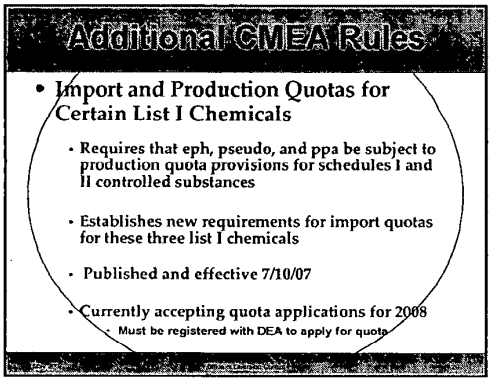
Penalties for Sellers

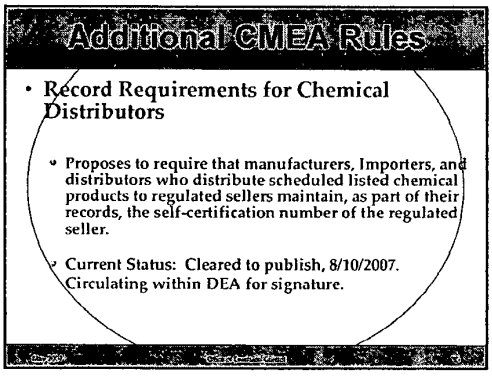
- First time offense subject to imprisonment **not more than one year**, a fine under Title 18, or both.
- Repeat violation (one or more prior convictions), subject to imprisonment **not more than two years**, a fine under Title 18, or both.
- A person who sells a scheduled listed chemical product at retail without being self-certified is subject to civil penalties **up to $10,000 per count**.
- Prohibition of sales of product.

Penalties for Purchasers

- Offenders are subject to imprisonment **not more than one year** and fines in accordance with Title 18.







Additional CMEA Rules

- **Notice of Transfer following Importation or Exportation**
  - Implements the **"spot market"** provisions of CMEA.
  - Importers, exporters, required to provide DEA with information on "down stream" customer and the amount to be transferred
  - Return declaration required once the importation, exportation, or international transaction has occurred.
  - Published on 4/9/2007. Rule became effective on 6/9/2007.

Additional CMEA Rules

- **Self-Certification Fee for Regulated Sellers**
  - **This rulemaking proposes to impose a fee for self-certification of regulated sellers of scheduled listed chemical products, based on DEA's costs for operation of this aspect of the Diversion Control Program.**
  - **Current Status: Cleared to publish on 8/7/2007. Circulating within DEA for signature**

Questions?

Regulatory Update

Mark W. Caverly, Chief
Liaison and Policy Section
Office of Diversion Control

Combat Methamphetamine Epidemic Act of 2005

- Title VII of USA Patriot Improvement and Reauthorization Act of 2005, March 2006 (Public Law 109-177)
- Purpose:
  - To provide greater controls of OTC products containing ephedrine, pseudoephedrine, and phenylpropanolamine.
- Retail Provisions became fully effective on September 30, 2006

CMEA Retail Rule

- Self-Certification
- Employee Training
- Maintain Records of Training
- Product Packaging (blister-packs)
- Product Placement
- Logbook (Manual or Electronic option)
  - Logbook information disclosed only as permitted
- Daily and 30-Day Sales/Purchase Limits

CMEA "Spot Market" Rule

- Applies to All List I and List II chemicals
- Interim Final Rule – April 9, 2007
- Effective June 8, 2007
- New DEA-486
  - Transferee and quantity of chemical to be transferred
  - Return declaration

Additional CMEA Rules

- Assessment of Annual Need
  - Circulating within DEA for signature
- Import and Production Quotas for Certain List I Chemicals
  - Published and effective 7/10/07
- Elimination of Exemption for Chemical Mixtures containing Ephedrine and/or Pseudoephedrine
  - Published 7/25/07, effective 8/24/07

Additional CMEA Rules

- Record Requirements for Chemical Distributors
  - Cleared to publish, circulating for signature
- Foreign Chain of Distribution
  - Accepted by OMB 8/1/07

Multiple CII Prescription Rule

- Permit practitioners to issue multiple prescriptions for C II substances to allow patients up to a 90-day supply.
- Provide greater control to physicians for prescribing Schedule II medications.
- Rule finalized within DEA, sent to OMB in June 2007

Controlled Substances Reexport Rule

- Controlled Substances Export Reform Act of 2005 authorizes export of controlled substances from US to another country for subsequent export to one or more other countries
- Schedules I, II, narcotic controlled substances in Schedules III, IV
- Final Rule sent to OMB in August 2007

Single Sheet DEA Form 222

- Rule proposes a new format for Official Order Form, DEA 222
- Single, pre-printed form
- Special paper, security features
- Rule sent to OMB for review on April 6, 2007

Multi-State Practice Clarification

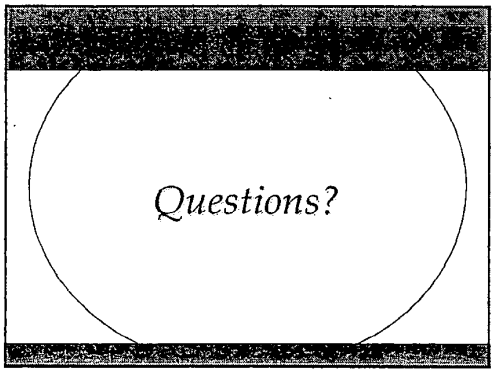
- Amended registration regulations to clarify requirement that when an individual practitioner practices in more than one state, a separate DEA registration for each State (21 CFR 1301.12)
- Final Rule published December 1, 2006, became effective January 2, 2007

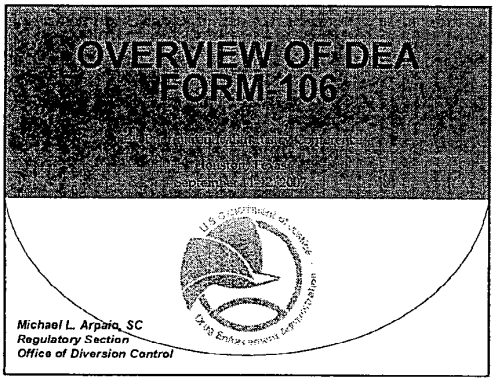
Iodine and Chemical Mixtures

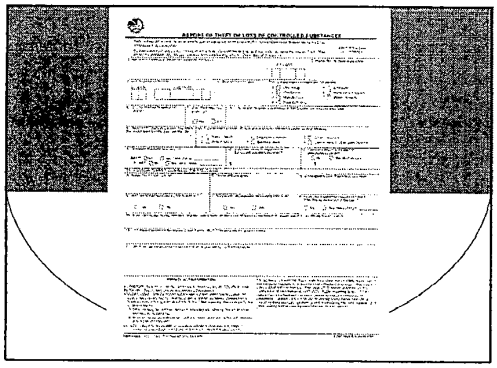
- Moves Iodine from a List II chemical to List I
- Controls chemical mixtures over 2.2%
- Reduces thresholds for regulated transactions to zero
- Adds import/export regulatory controls
- Final Rule published on 7/2/07, Effective on 8/1/07

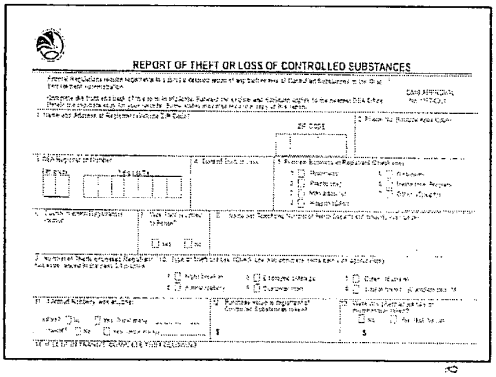
Pending Regulations/Policies

- Policy Working Group
  - Locum Tenens
  - Reverse Distributors
  - Agent of a Practitioner
  - Telepharmacy, Telemedicine, and Remote Dispensing Sites
  - "Medical Bag" Supply
  - Emergency Kits in LTCFs



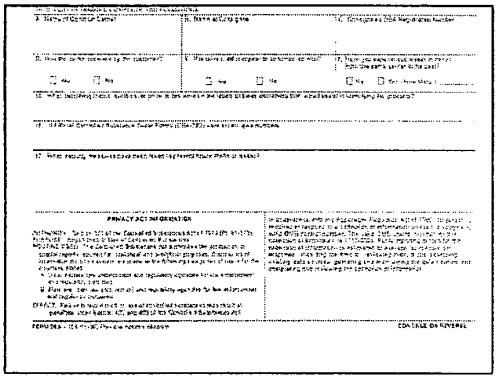

OVERVIEW OF DEA
FORM 106
Michael L. Arpaio, SC
Regulatory Section
Office of Diversion Control




REPORT OF THEFT OR LOSS OF CONTROLLED SUBSTANCES

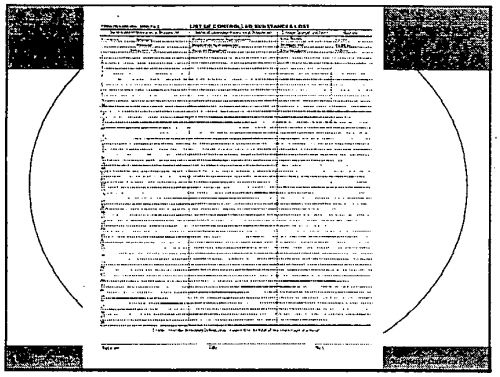
REPORT OF THEFT OR LOSS OF CONTROLLED SUBSTANCES

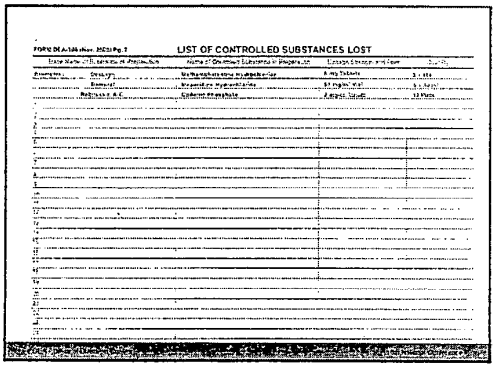
- Date of Theft or Loss
- Notifying Police
- Number of Thefts
- Type of Theft or Loss
- Purchase Value of the Controlled Substances
- Pharmaceuticals or Merchandise Taken

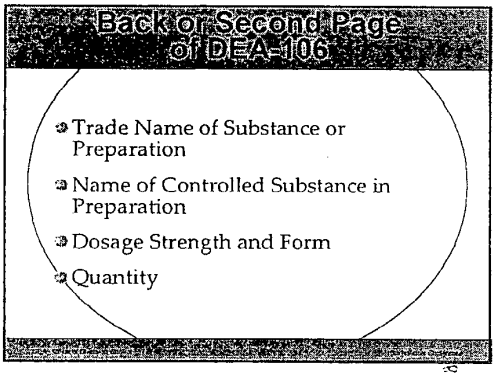


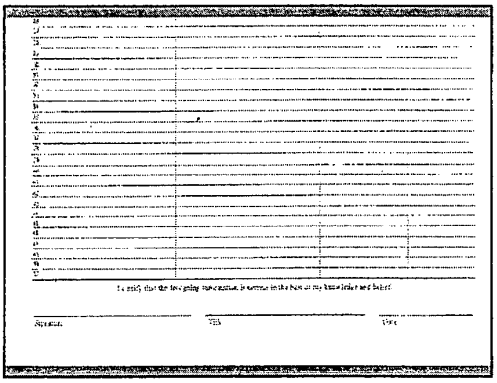
REPORT OF THEFT OR LOSS OF CONTROLLED SUBSTANCES

- Lost in Transit
- Order Forms
- What Security Measures









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- Signature
- Title
- Date of Form

TITLE 21 CODE OF FEDERAL REGULATIONS PART 1301.74 (c)

- The registrant shall notify the DEA within one business day *of discovery* of the theft or loss.
- All in-transit losses of controlled must be reported.
- The registrant shall complete and submit a DEA Form 106.

WHAT CONSTITUTES A SIGNIFICANT LOSS?

- The actual quantity of controlled substance lost in relation to the type of business.
- The specific controlled substances lost.
- Whether the loss of the controlled substances can be associated with access to those controlled substances by specific individuals, or whether the loss can be attributed to unique activities that may take place involving the controlled substances.

WHAT CONSTITUTES A SIGNIFICANT LOSS?

- A pattern of losses over a specific time period, whether the losses appear to be random, and the results of efforts taken to resolve the losses; and if known;
- Whether the specific controlled substances are likely candidates for diversion;
- Local trends and other indicators of the diversion potential of the missing controlled substances.

Questions?